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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,994	02/27/2001	Edmonds Taylor Brian	X-12239	6826

7590

10/12/2004

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EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/763,994

**Applicant(s)**

BRIAN, EDMONDS TAYLOR

**Examiner**

David S Romeo

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-36 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 0204.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

The amendment filed 08/11/2004 has been entered. Claims 32-36 and 38 are pending and being examined.

5           The examiner called and left a message for Caren Geppert on 08/20/2004 regarding a proposed examiner's amendment. The examiner proposed: in claim 32, line 1, delete "latent hLTBP-3"; in claim 33, line 1, delete "hLTBP-3"; in claim 38, line 2, delete "an hLTBP-3" and insert --a--. However, agreement could not be reached.

### ***Claim Rejections - 35 USC § 112***

Claims 32-36, 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. When the claims are read in light of the specification the intended scope of the term “hLTBP-3 polypeptide” becomes unclear.

15 The metes and bounds are not clearly set forth.

Applicant argues that the specification at page 18 provides a table of possible amino acid substitutions, that modifications made in accordance with the table are generally expected to retain the activity of the parent molecule, that the functionality of these polypeptides is clearly indicated in the name “hLTBP-3,” that therefore all genus members bind TGF- $\beta$ , and that therefore the scope of the claims is clear. Applicant's arguments have been fully considered but they are not persuasive. The amino acid substitutions in the table on page 18 of the specification are merely exemplary and do not limit the claimed subject matter in any way. The statement that “[m]odifications of

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hLTBP-3 polypeptides ... are generally expected to retain the biological activity of the parent molecule” (page 17) does not limit the biological activity of the modified hLTBP-3 polypeptides. Furthermore, the specification states that “[n]on-limiting mutants that can enhance, decrease, or maintain at least one of the listed activities are contemplated” (paragraph bridging pages 16-17) and “[a]lso contemplated by the present invention are proteins that are functionally related to hLTBP-3” (page 17, full paragraph 1). These statements indicate that the functionality of the claimed polypeptides is not clearly indicated in the name “hLTBP-3,” and that not all genus members bind TGF- $\beta$ . Therefore, the intended scope of the term “hLTBP-3 polypeptide” is unclear. The metes and bounds are not clearly set forth.

Claims 32-36, 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the specification at page 18 provides a table of possible amino acid substitutions, that modifications made in accordance with the table are generally expected to retain the activity of the parent molecule, that the functionality of these polypeptides is clearly indicated in the name “hLTBP-3,” that therefore all genus members bind TGF- $\beta$ , and that therefore the scope of the claims is clear. Applicant's arguments have been fully considered but they are not persuasive. The amino acid substitutions in the table on page 18 of the specification are merely exemplary and do not

limit the claimed subject matter in any way. The statement that “[m]odifications of hLTBP-3 polypeptides ... are generally expected to retain the biological activity of the parent molecule” (page 17) does not limit the biological activity of the modified hLTBP-3 polypeptides. Furthermore, the specification states that “[n]on-limiting mutants that  
5 can enhance, decrease, or maintain at least one of the listed activities are contemplated” (paragraph bridging pages 16-17) and “[a]lso contemplated by the present invention are proteins that are functionally related to hLTBP-3” (page 17, full paragraph 1). These statements indicate that the functionality of the claimed polypeptides is not clearly indicated in the name “hLTBP-3,” and that not all genus members bind TGF- $\beta$ .

10 Therefore, the specification and claim do not indicate what distinguishing attributes are shared by the members of the claimed genus of “hLTBP-3” polypeptides. Thus, applicant was not in possession of the claimed genus.

***Claim Rejections - 35 USC § 101***

15 Claims 33-36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant argues that the claims have been amended according to the examiner’s suggestion and request that the rejection be withdrawn. Applicant’s arguments have been fully considered but they are not persuasive. Claim 33 has not been amended to indicate  
20 the hand of the inventor, e.g., by insertion of “Isolated” or “Purified.” Therefore, the claims, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the

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hand of man, the naturally occurring products are considered non-statutory subject matter.

**New Formal Matters, Objections, and/or Rejections:**

5 ***Claim Rejections - 35 USC § 112***

Claims 32-36, 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had  
10 possession of the claimed invention. Support for the recitation of “latent hLTBP-3 polypeptide” (claim 32) cannot be found in the disclosure as originally filed and Applicant does not indicate in the 08/11/2004 amendment where the specification supports this amendment, which raises the issue of new matter.

15 Claims 32-36, 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 32-36, 38 are indefinite over the recitation of “latent hLTBP-3 polypeptide” (claim 32). The term “latent” suggests that some activity of hTLBP-3 is present or potential but not evident or active. It is unclear  
20 which activity of hLTBP-3 is present or potential but not evident or active. The metes and bounds are not clearly set forth. It is suggested that the term “latent” be deleted.

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### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in  
5 this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP  
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37  
CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE  
MONTHS from the mailing date of this action. In the event a first reply is filed within  
10 TWO MONTHS of the mailing date of this final action and the advisory action is not  
mailed until after the end of the THREE-MONTH shortened statutory period, then the  
shortened statutory period will expire on the date the advisory action is mailed, and any  
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the  
advisory action. In no event, however, will the statutory period for reply expire later than  
15 SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE  
DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON  
MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE  
UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.

20 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL  
CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHT FAX NUMBERS:


BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

25 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A  
NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE  
DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO  
PRIMARY EXAMINER  
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